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| EXAMINER | |
|---|---|
| SALMON, KATHERINE D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/798,652 | GUO, YONGJUN | |
| | Examiner | Art Unit | |
| | Katherine Salmon | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *6-24 and 29-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 25-28, 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/27/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. This action is in response to the papers filed 8/22/2006. Currently, Claims 1-33 are pending. Claim 34 has been canceled. Claims 6-24 and 29-32 have been withdrawn as being drawn to a nonelected invention.

2. The following rejections are applied as necessitated by amendment or are reiterated. Response to arguments follows.

3. This action is FINAL.

### *Election/Restrictions*

4. The reply traverses the finality of the restriction requirement. The reply asserts that the method claims be rejoined with any allowable product claims (p. 7 2nd paragraph). It is noted that the restriction requirement was appropriate. At this time there are no allowable product claims, therefore, the methods claims have not yet been rejoined. Upon allowability of the product claims a rejoinder for the method claims may be done.

### *Information Disclosure Statement*

5. It is noted that the Information Disclosure statement filed March 22, 2006 was considered by the Examiner with the previous office action mailed 4/18/2006. An additional copy of this IDS with the Examiner's signatures is provided with this action. It is noted, however, that the listing of the references on pages 27-28 of the specification

have not been considered unless the references were placed on the filed Information Disclosure statement.

## Withdrawn Objections

**6.** The objection to the Drawings, specifically Figure 3, made in section 6 of the previous office action, is moot in view of the amended Figure 3, which clearly reflects the differences between the African and Caucasian populations.

## Withdrawn Rejections

7. The rejection of Claims 1 –5, 25-28 and 33-34 made under 35 USC 112/Enablement, made in Section 7 of the previous office action, is moot in view amendment to claim 2, the addition of human in claim 25 and the declaration present in the reply. Specifically the reply clarified the relationship of Genbank Accession Y12377 and SEQ ID No. 1. The reply asserts that the FGF-3 gene in the examples was the sequence of SEQ ID No. 1 and not the GenBank Accession Y12377.

## *Maintained Rejections or Rejections Necessitated by Amendment*

### *Claim Rejections - 35 USC § 112-Written Description*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-5, 25-28, and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to an isolated nucleic acid molecule comprising the sequence of SEQ ID No. 1. Claim 2 is drawn to an isolated nucleic acid molecule comprising a sequence fully complementary complementary to the sequence of SEQ ID No. 1. Claims 3-4 are drawn to a vector wherein the reporter gene sequence encodes luciferase. Claim 5 is drawn to a host cell. Claim 25 is drawn to a kit comprising a first oligonucleotide probe which anneals specifically with a target portion of the mammal's genome, wherein said first probe comprises a first fluorescent label and a first fluorescence quencher attached to separate nucleotide residues thereof and said target portion includes the nucleotide residue located at position 69 of SEQ ID No. 1 and a pair of primers for amplifying a reference portion of the FGF-3 gene wherein said reference portion includes the nucleotide residue located at position 69 of SEQ ID No. 1. Claim 26 is drawn to a kit including DNA polymerase having 5' to 3' exonuclease activity. Claim 27 is drawn to a kit further comprising a second oligonucleotide probe, wherein said first probe is completely complementary to said target portion if the nucleotide residue located at position 69 of SEQ ID No. 1 is cytosine and said second oligonucleotide probe is completely complementary to said target portion if the nucleotide residue located at position 69 of SEQ ID No. 1 is thymine. Claim 28 is drawn to a kit further including an instructional material. Claim 33 is drawn to a microarray having at least one oligonucleotide probe that can anneal with a target portion of a

mammal's genome, wherein the target portion includes the nucleotide residue located at position 69 of SEQ ID No. 1. Claim 34 is drawn to a microarray wherein at least one oligonucleotide probe consists essentially of nucleotide sequences selected from the group consisting of SEQ ID No. 6 and 7.

The claims do not describe the number or identity of nucleotides flanking the recited nucleic acid fragment of SEQ ID No. 1. The claims encompass nucleic acids, which comprise any nucleic acid variant of any size, fragments of SEQ ID No. 1, and sequence, which are complementary to SEQ ID No. 1 for any number of nucleotides. The claims encompass variants, which include nucleotide substitutions, additions, deletions, translocations, and truncations. Claims encompass any number of sequences, which must include only the cytosine of position 69 of SEQ ID No. 1. The specification does not describe the sequences encompassed by "fully complementary to SEQ ID No. 1"

The claims also encompass a large genus of sequences from any mammal. The specification does not describe SEQ ID no. 1 in any mammalian species other than human.

The specification does not teach the percent structural identity needed for a sequence to be considered FGF3. The specification also does not indicate how much variation a sequence may have; therefore, the claims with regard to the "target" sequences can be any number of variations, mutations, or homologs.

The genus of the claimed nucleic acids molecules encompasses substantial variability among the species of nucleic acids, but only a few mutations have been described. The genus of the claimed invention encompasses a large variable genus of mutants, variants, and homologs from any source

The specification fails to sufficiently describe the claimed invention in clear and exact terms so that a skilled artisan would recognize that the applicants were in possession of the claimed invention at the time of filing.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) In the instant case, the specification fails to teach the necessary common attributes or features of the genus of encompassed nucleic acids and mammalian species in view of the species disclosed. As such, one of skill in the art would not recognize that applicant was in possession of the genus of nucleic acids and polymorphisms encompassed by the broadly claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an

invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The sequences encompassed by the claims do not meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly diverse. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

**Response to Arguments**

The reply asserts the sequence of the FG3 gene containing the polymorphism associated with cancer susceptibility is provided in the specification (p. 11 1st paragraph). The reply asserts the present claims as amended no longer read on variants and fragments of SEQ ID No. 1 (p. 11 3rd paragraph). These arguments have been thoroughly considered but have not been found persuasive.

The claims as written broadly encompass a much larger genus then just the FGF3 gene. Claim 1 is drawn to an isolated nucleic acid molecule comprising the sequence of SEQ ID No. 1. The claims do not set forth the number or identity of nucleotides flanking the recited sequence. Accordingly, the claims encompass mutants, variants, and homologs from any source not just the FGF3 gene. The claims encompass any number of nucleotides flanking SEQ ID No. 1, whereas the specification only describes SEQ ID No. 1 in terms of the FG F3 gene. Further, the amendment to Claim 2 does not limit the claim to the complement of SEQ ID No. 1. Any fragment of SEQ ID NO. 1, which is 100% identical to SEQ ID NO. 1, would be fully complementary to SEQ ID No. 1 and would include any number of fragments of SEQ ID NO. 1.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Genebank Accession Number (Y12377 March 2, 2000)

With regard to Claim 2, Accession Y12377 a FGF-3 sequence which differs from SEQ ID NO. 1 in one position. Accession Y12377 is identical to the instant specification

SEQ ID NO. 1 for nucleotides 1-69 and 71-564 of the instant application (nucleotides 4945-5013 and 5015-5508 of Y12377). At position 69 (position 5013 of Y12377) there is a "C". The two sequences differ at position 70 (position 5014 of Y12377) in which the instant application SEQ ID No. 1 possesses a "G" whereas Y12377 possess a "T". Therefore Accession Y12377 encompasses the claim language of "complementary" to SEQ ID No. 1.

**Response to Arguments**

The reply asserts Claim 2 has been amended to recite that the nucleic acid molecule encompassed by the claim is fully complementary to SEQ ID No. 1. This arguments has been thoroughly considered but have not been found persuasive.

Though Accession Y12377 is not the complement of SEQ ID No. 1 because it differs at position 70, the nucleotides which are 100% identical would however be considered "fully complementary" because the fragments are 100% identical.

10. Claims 2 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5474796 December 12, 1995).

The claims are drawn to an isolated nucleic acid molecule that comprises at least 10 nucleotides. Brennan teaches an array which contains oligonucleotides with 10 nucleotides each (see Column 9, lines 49-50). Brennan teaches that the total array represents every possible permutation of the 10-mer oligonucleotide (see Column 9, lines 53-55). With regard to Claim 2, Brennan teaches the possible 10-mer

combination which is 100% complementary to the instant application's Seq ID No. 1 and would be considered "fully complementary".

With regard to Claim 33, Brennan teaches a 10-mer array (See column 9, lines 49-50). Therefore Brennan teaches a microarray with at least one probe that can anneal to a target which includes the nucleotide residue located at position 69 of SEQ ID No. 1 and the target portion is selected from the group consisting of SEQ ID No. 6 and 7.

**Response to Arguments**

The reply asserts Claim 2 has been amended to recite that the nucleic acid molecule encompassed by the claim is fully complementary to SEQ ID No. 1. The reply asserts that Claim 33 has been amended to recite the probes of SEQ ID No. 6 and 7 and that Brennan does not teach a microarray for the detection of a SNP in the untranslated region of the FGF3 gene for detection of cancer susceptibility (p. 12 3rd paragraph). This arguments has been thoroughly considered but have not been found persuasive.

A 10 mer of Brennan is a complement of SEQ ID No. 1, the 10-mers which are 100% identical would be considered "fully complementary" because the fragments are 100% identical to 10 mer fragments of SEQ ID No. 1. Further the microarray is a composition claim comprising at least one probe that can anneal with a target portion of the human genome. A 10 mer of Brennan on an array would hybridize to portions of the human genome including fragments, which contain the nucleotide residue located at

position 69 of SEQ ID No. 1. Claim 33 is being interpreted for this rejection such that SEQ ID No. 6 and 7 are the target position.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Katherine Salmon
Examiner
Art Unit 1634

BJ FORMAN, PH.D.
PRIMARY EXAMINER